DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 23, 2015

Texas Medical Technologies, Inc.
% Viviana Gonzalez
Consultant
Pomamed Consulting LLC
Po Box 9818
San Juan, PR 00908-0818

Re: K142817
Trade/Device Name: IntraNovo 25 Microcatheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO
Dated: March 9, 2015
Received: March 18, 2015

Dear Viviana Gonzalez,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142817

Device Name

IntraNovo 25 Microcatheter

Indications for Use *(Describe)*

The IntraNovo 25 Microcatheter is intended for the infusion of contrast media into all peripheral vessels up to and including the cervical vessels, all vessels in the lower and upper extremities, and all coronary vessels. The Microcatheter is also intended for drug infusion in intra-arterial therapy and infusion of embolic materials for hemostasis. The Microcatheter should not be used in cerebral vessels.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K142817 510(k) Summary

1 – Company Information & Contact Person

Company Name:	Texas Medical Technologies Inc.
Company Address:	9005 Montana Ave. Ste. A El Paso, Texas 79925
Telephone:	(915) 774-4321
Fax:	(915) 774-4323
Contact Person:	Cesar Rios, Quality Assurance & Regulatory Manager
Date Prepared:	4/22/2015

2 – Device Name & Classification

Proprietary Name:	IntraNovo 25
Common Name:	Microcatheter
Classification Name:	Diagnostic Intravascular Catheter
Regulation Number:	21 CFR 870.1200
Product Code:	DQO
Device Class:	II

3 – Predicate Device

Legally Marketed Substantially Equivalent Predicate Device

Proprietary Name:	PROGREAT
Company Name:	Terumo Medical Corporation
Common Name:	Catheter
Classification Name:	Diagnostic Intravascular Catheter
Regulation Number:	21 CFR 870.1200
Product Code:	DQO
Device Class:	II
510(k) Number	K033583

4 – Device Description

The IntraNovo 25 Microcatheter (the "IntraNovo 25" or the "Microcatheter") is an infusion catheter intended for intravascular use. The Microcatheter consists of a single lumen. The shaft consists of a lubricous inner liner made from polytetraflouroethylene (PTFE) with a stainless steel coil over the inner liner. The outer liner consists of different lengths of colored polyether block amide with varying durometers hardness. A lubricious hydrophilic coating covers the distal end of the IntraNovo 25 Microcatheter. Depending on the model, one or two radiopaque marker bands are placed at the distal end of the Microcatheter and

above the stainless steel coil. A polycarbonate hub is attached to the proximal end of the Microcatheter with a strain relief placed over the distal end of the hub.

The device shaft has an outer diameter of 2.9 French size on the proximal end and 2.7 French size on the distal end with an inner diameter of 0.025" throughout the shaft. The device is available in lengths of 110 cm, 130 cm, and 150 cm.

The following accessories are included with the Microcatheter: a stainless steel steam shaping mandrel to allow for manual shaping of the distal tip and a 3.0 mL syringe.

The device is supplied sterile and is intended for single use.

The following table lists the models and sizes available for the IntraNovo 25 Microcatheter.

Table 4.1. IntraNovo 25 Microcatheter Models and Sizes

Design & Development Model Number	Commercial Model Number	Shaft Length (cm)	Outer Diameter		Inner Diameter	Marker Band Configuration	Tip Shape
			Distal	Proximal			
SMC-25110-S	MC-2711-2SN	110	2.7 Fr.	2.9 Fr.	0.025"	2 Marker Bands	Straight (shapeable)
SMC-25130-S	MC-2713-2SN	130	2.7 Fr.	2.9 Fr.	0.025"	2 Marker Bands	Straight (shapeable)
SMC-25150-S	MC-2715-2SN	150	2.7 Fr.	2.9 Fr.	0.025"	2 Marker Bands	Straight (shapeable)
SMC-25110-1S	MC-2711-1SN	110	2.7 Fr.	2.9 Fr.	0.025"	1 Marker Band	Straight (shapeable)
SMC-25130-1S	MC-2713-1SN	130	2.7 Fr.	2.9 Fr.	0.025"	1 Marker Band	Straight (shapeable)
SMC-25150-1S	MC-2715-1SN	150	2.7 Fr.	2.9 Fr.	0.025"	1 Marker Band	Straight (shapeable)

5 – Indications for Use

The IntraNovo 25 Microcatheter is intended for the infusion of contrast media into all peripheral vessels up to and including the cervical vessels, all vessels in the lower and upper extremities, and all coronary vessels. The Microcatheter is also intended for drug infusion in intra-arterial therapy and infusion of embolic materials for hemostasis. The Microcatheter should not be used in cerebral vessels.

6 – Summary of Technological Characteristics Comparison

Based on a comparison of the indications for use, fundamental design, technology and principles of operation, materials, performance, sterilization, and packaging, it is determined that the IntraNovo 25 Microcatheter is substantially equivalent to the predicate device. Table 6.1 below provides a comparison of the IntraNovo 25 Microcatheter and the predicate.

Table 6.1 Comparison of the IntraNovo 25 Microcatheter and the Predicate Device.

Technical Characteristics / Principle of Operation	IntraNovo 25 Microcatheter	PROGREAT Catheter (Predicate)	Substantially Equivalent?
Length	100cm - 150cm	100cm - 150cm	Yes
Outer Diameter	Distal: 2.7 Fr.	Distal: 2.7 Fr.	Yes
	Proximal 2.9 Fr.	Proximal: 2.9 Fr.	Yes
Inner Diameter	0.025”	0.025”	Yes
Maximum Pressure	5,171 kPa (750 psi)	5,171 kPa (750 psi)	Yes
Distal Curve	Straight (shapeable)	Straight (shapeable)	Yes
Inner Liner Material	Polytetraflouroethylene (PTFE)*	Polytetraflouroethylene (PTFE)	Yes
Coil Reinforcement Material	Stainless Steel*	Tungsten	Yes
Radiopaque Marker	Platinum/Iridium*	Tungsten coil and/or Platinum marker band	Yes
Outer Shaft Material	Polyether Block Amide*	Unknown	Yes
Luer Material	Polycarbonate*	Unknown	Yes
Luer Connector	Female Luer Connector*	Female Luer Connector	Yes
Hydrophilic Coated	Yes*	Yes	Yes
Anatomical Site Use	Peripheral, Coronary	Peripheral, Coronary	Yes
Supplied Accessories	Shaping Mandrel, Injection Syringe	Shaping Mandrel, Injection Syringe	Yes
Delivery to Site	Over-the-wire	Over-the-wire	Yes
Guidewire Compatibility	Maximum 0.021”	Maximum 0.021”	Yes
Packaging	Polyethylene Hoop and Tyvek Pouch	Polyethylene Hoop and Tyvek Pouch	Yes
Sterilization	EtO Gas	EtO Gas	Yes

* Denotes a patient-contacting material.

7 – Testing Summary

The following bench tests were performed to evaluate the design elements and performance characteristics of the IntraNovo 25 Microcatheter and to demonstrate substantial equivalence to the predicate device. The IntraNovo 25 Microcatheter met the predetermined acceptance criteria. Testing was performed on non-aged devices (T=0) as well as on devices subject to 2 years of accelerated aging (T=2). Tests results show that the IntraNovo 25 Microcatheter is substantially equivalent to the predicate device.

7.1- Bench Testing Table

Table 7.1 below provides a summary of the bench testing performed on the IntraNovo 25 Microcatheter.

Table 7.1. Bench Testing Performed on the IntraNovo 25 Microcatheter.

Test #	Test Name	Applicable Standard or Internal Test Method	Test Results (T=0) and (T=2)
1	Guidewire & Guide Catheter Compatibility	Internal Test Method	T=0 Pass T=2 Pass
2	In-Vitro Track Force	Internal Test Method	T=0 Pass T=2 Pass
3	Durability of Hydrophilic Coating	Internal Test Method	T=0 Pass T=2 Pass
4	Lubricity of Hydrophilic Coating	Internal Test Method	T=0 Pass T=2 Pass
5	Tip Shape Retention	Internal Test Method	T=0 Pass T=2 Pass
6	Static Burst Pressure	ISO 10555	T=0 Pass T=2 Pass
7	Dimensional & Physical Attributes	ISO 10555	T=0 Pass T=2 Pass
8	Corrosion Resistance	ISO 10555	T=0 Pass T=2 Pass
9	Dynamic Burst Pressure	Internal Test Method	T=0 Pass T=2 Pass
10	Air Leak	Internal Test Method	T=0 Pass T=2 Pass
11	Liquid Leakage	Internal Test Method	T=0 Pass T=2 Pass
12	Tensile Strength	ISO 10555	T=0 Pass T=2 Pass
13	Flow Rate	Internal Test Method	T=0 Pass T=2 Pass
14	Kink Resistance	Internal Test Method	T=0 Pass T=2 Pass
15	Radiopacity	ASTM-F640-12	T=0 Pass T=2 Pass
16	Torque to Failure	Internal Test Method	T=0 Pass T=2 Pass
17	Catheter Stiffness	Internal Test Method	T=0 Pass T=2 Pass
18	Packaging Integrity	ASTM F-88-09 ASTM-1929-98	T=0 Pass T=2 Pass
19	Therapeutic Agents	Internal Test Method	T=0 Pass T=2 Pass
20	Female Luer Hub Verification	ISO 594	T=0 Pass T=2 Pass
21	Shipping and Transportation Simulation	ISTA 3PA	T=0 Pass T=2 Pass
22	Coating Integrity	Internal Test Method	T=0 Pass T=2 Pass
23	Torque Response	Internal Test Method	T=0 Pass T=2 Pass
24	Particulate Evaluation	USP <788>	T=0 Pass T=2 Pass

7.2 – Biocompatibility

The IntraNovo 25 Microcatheter is classified as an Externally Communicating Device, Circulating Blood, Limited Contact (≤24 hours). Biocompatibility testing was performed in accordance with ISO 10993 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process" (2009). Table 7.2 below describes the testing performed to determine biocompatibility.

Table 7.2. Summary of Biocompatibility Testing for the IntraNovo 25 Microcatheter

Test Name	Test Description	Test Results
Cytotoxicity - Test	Cytotoxicity – MEM Elution Test (ISO 10993-5:2009)	Pass
	Cytotoxicity-MTT Quantitative Evaluation (ISO 10993-5:2009)	Pass
Sensitization - Test	Maximization Test for Delayed-Type Hypersensitivity Test (ISO 10993-10:2010)	Pass
Irritation - Test	Intracutaneous (Intradermal) Reactivity Test (ISO 10993-10:2010)	Pass
Systemic Toxicity - Test	Acute Systemic Toxicity Test (ISO 10993-11:2006)	Pass
Pyrogenicity Test	Pyrogen Test in Rabbits (ISO10993-11/USP 37 <151>, rev. 5/2014)	Pass
Hemolysis – Test	Hemolysis, Direct and Extraction Method (ASTM 756-08)	Pass
Coagulation	Prothrombin Time Assay	Pass
Complement Activation - Test	Complement Activation	Pass
In vivo Thrombogenicity - Test	Thromboresistance in Dogs	Pass

8 - Sterilization Testing Summary

Validation Sterilization Process	Sterility Assurance Level (SAL)	Validation Result
Ethylene Oxide Gas	10^{-6}	Pass

9 – Conclusion

The IntraNovo 25 Microcatheter is substantially equivalent in intended use, fundamental design, technology and principles of operation, materials, performance, sterilization, and packaging to the predicate device. Differences between the devices do not raise any new issues of safety or effectiveness.